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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,983	12/19/2001	Bartley Dean Maxon	DC4969	4816

137 7590 03/12/2002

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,983

Applicant(s)

MAXON ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for linear silicone polyether disclosed in paragraphs 0011-0017 and Table 1, does not reasonably provide enablement for other linear silicone polyethers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,

- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines a "linear silicone polyethers".

Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "linear silicone polyethers" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "linear silicone polyethers", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nonionic organic emulsifiers disclosed in paragraph 0031 in the specification, does not reasonably provide enablement for other nonionic organic emulsifiers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. See above eight different factors.

Applicant fails to set forth the criteria that defines "nonionic organic emulsifiers". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "nonionic organic emulsifiers" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "nonionic organic emulsifiers", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schilling, Jr. et al. (US Patent 4,150,048), Schulz, Jr. et al. (US Patent 5,654,362 from the IDS received December 19, 2001), Remington (Remington's Pharmaceutical Sciences, 18th ed., 1990, page 1314), Zhang (US Patent 5,889,108) in view of Lin et al. (US Patent 6,207,717 B1 from the IDS received December 19, 2001).

Schilling, Jr. et al. teaches a linear silicone polyether which is useful as surfactant in the preparation of aerosol for shaving cream (See particularly the abstract; also col. 6, lines 2-3). Schilling, Jr et al. teaches the weight percent of linear silicone polyether to be 0.5-2.0 (See particularly col. 13, line 12-13).

Schulz, Jr et al. teaches a α,ω -diene-crosslinked silicone elastomer to be useful in silicone paste which can be used in the preparation of cosmetic products such as shaving lotion and facial cleansers (See particularly the abstract and claim 13). Schulz, Jr et al. teaches the weight percent of α,ω -diene-crosslinked silicone elastomer to be about 7.8% (See particularly col. 6, lines 42-65, Example III).

Remington teaches that polysorbate 20 is a commonly used as a nonionic organic surfactant (See page 1314).

Zhang teaches decamethylcyclopentasiloxane, a thinckening solvent, with a silicone elastomer or silicone paste are useful in preparation of emulsion useful for shaving lotion, shaving lathers or delivery systems of vitamins (See particularly the abstract, also col. 7, lines 12-29).

The references do not expressly teach the composition comprising the combination of linear silicone polyether, α,ω -diene-crosslinked silicone elastomer, and

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a nonionic organic emulsifier. The references do not expressly teach the composition comprising the combination of linear silicone polyether, α,ω -diene-crosslinked silicone elastomer, a nonionic organic emulsifier, decamethylcyclopentasiloxane, and vitamin E. The references do not expressly teach. The references do not expressly teach the weight percent of nonionic organic emulsifier to be 0.1-4.0.

Lin et al. teaches a water-in-oil emulsion comprising vitamin E and an elastmeric silicone polyether which can be used in the preparation of shaving soaps, shaving lotion, and shaving lathers (See particularly the abstract; also col. 12, line 14-15).

It would have been obvious to one skill in the art when the invention was made to employ linear silicone polyether, α,ω -diene-crosslinked silicone elastomer, polysorbate 20 (nonionic organic emulsifier), decamethylcyclopentasiloxane (a solvent), and vitamin E into a single composition. It would have been obvious to one skill in the art when the invention was made to employ the nonionic organic emulsifier in the weight percent herein.

One of ordinary skill in the art would have motivated to employ linear silicone polyether, α,ω -diene-crosslinked silicone elastomer, polysorbate 20 (nonionic organic emulsifier), decamethylcyclopentasiloxane (a solvent), and vitamin E into a single composition because combining two or more agents which are known to be useful to formulate shaving creams and lotions individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. One of ordinary skill in the art would have motivated to employ the nonionic organic emulsifier in the weight percent herein because The optimization of result effect

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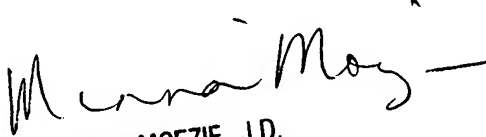
parameters (e.g., the amount of the excipients such as surfactant) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
March 5, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600